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October 21, 2024

**VIA ECF**

Special Master the Honorable Thomas Vanaskie  
Stevens & Lee  
1500 Market Street, East Tower  
18th Floor  
Philadelphia, PA 19103

**Re: *In re: Valsartan, Losartan, and Irbesartan Products Liability Litigation.*, U.S. District Court for the District of New Jersey; Case No. 1:19-md-02875**

Dear Special Master Vanaskie:

This letter is to provide Defendants' positions with respect to the topics on the agenda for the Status Conference with Your Honor on October 22, 2024. Defendants do not expect the need to discuss any confidential materials as part of these agenda items.

- a. Identification of all bellwether cases for trial, which the parties have previously agreed to, and for which the Court's text order of October 10, 2024 (ECF No. 2899) directed the parties to prepare.**

There are currently 28 cases in the bellwether pool. In order to move these cases toward trial in an expedited manner, Defendants believe that the best course is

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to: (1) confirm that all 28 Plaintiffs still intend to pursue their claims; (2) narrow the bellwether pool to a reasonable number of six cases that would be worked up for sequential trials; and (3) ultimately select two of the six cases for separate individual trials at a time to be determined by the parties and the Court.

In January 2021, the parties each selected and simultaneously identified 15 personal injury plaintiffs as potential bellwether trial candidates in this MDL proceeding at the direction of the Court. Plaintiffs and Defendants both picked two of the same cases, resulting in a total of 28 cases in the Bellwether Trial Pool.<sup>1</sup> The parties conducted limited plaintiff-specific fact discovery in these cases, which included deposing the 28 Plaintiffs and two treating/prescribing physicians per Plaintiff. Thus, additional discovery is needed before the cases will be trial ready.

In order to efficiently move toward personal injury bellwether trials, Defendants propose the following:

1. By October 29, Plaintiffs should be required to inform Defendants and the Court whether any of these 28 previously-selected bellwether candidates no longer intend to pursue their claims to trial.

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<sup>1</sup> The parties' disclosures were previously filed with the Court at ECF No. 969-1 (Plaintiffs' picks) and 969-2 (Defendants' picks) and are re-attached here as Exhibit A and Exhibit B.

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2. By November 12, Plaintiffs should be required to produce updated Plaintiff Fact Sheets (“PFSs”) with updated and new (to the extent appropriate) document productions and medical record authorizations for each of the remaining bellwether candidates.
3. By November 19, the parties should be required to meet and confer in an attempt to agree on the selection of six Plaintiffs from that pool whose cases will be worked up for trial. If the parties are unable to agree within that time frame, the Court should randomly select six cases from the pool as the bellwether Plaintiffs. Courts and commentators recognize that absent agreement between the parties, a random selection of test cases is preferable as it ensures the selection of representative cases and avoids skewing the data produced. *See* MCL § 22.315 (citing *In re Chevron U.S.A., Inc.*, 109 F.3d 1016, 1019 (5th Cir. 1997) (“the sample must be a randomly selected one of sufficient size so as to achieve statistical significance . . . .”)); *see also* Felipe Villalón, Different Bells for Different Wethers: Random Sampling and Other Bellwether Selection Trends in Products Liability MDLs, 55 Conn. L. Rev. 501, 523 (2023) (“Thus far, random sampling has been broadly shown to be effective for massive MDLs.”).

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4. By November 26, the parties should be required to submit a proposed case management order for the six bellwether Plaintiffs whose cases will be worked up for trial, setting deadlines for remaining fact and expert discovery and pre-trial briefing leading up to trials. These deadlines would include:

- Close of Plaintiff-specific fact discovery;
- Pleadings, including any amendments and updated Short Form Complaints that comply with the Court's prior motion to dismiss rulings from Plaintiffs, and answers from Defendants;
- Plaintiffs' case specific expert reports and depositions;
- Defendants' case specific expert reports and depositions;
- Rule 702 and summary judgment motions, oppositions to such motions, and replies;
- Any motion by plaintiffs to consolidate cases for trial, oppositions to any such motion and a reply;
- Motions in limine, witness and exhibit lists, PTO, jury instructions and other pretrial exchanges; and
- Final pretrial hearing.

5. If any of the six selected bellwether Plaintiffs decide to dismiss their claims prior to trial, the dismissals should be with prejudice and Defendants should be entitled to pick a replacement Plaintiff from the remaining cases in the initial pool of 28 candidates. *See* Melissa J. Whitney, Federal Judicial Center & Judicial Panel on Multidistrict Litigation, *Bellwether Trials in MDL Proceedings: A Guide for Transferee Judges* 30 (2019) (to mitigate gamesmanship behavior, the transferee judge should “allow defendants to choose the replacement

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case where plaintiffs voluntarily dismiss a bellwether case”); Bolch & Duke Guide, at 26-27 (strategic behaviors to manipulate the bellwether process can be mitigated by “allowing defendants to select the replacement for any bellwether case that plaintiffs choose to dismiss.”); *see also In re FEMA Trailer Formaldehyde Prod. Liab. Litig.*, 628 F.3d 157, 162, 163 (5th Cir. 2010) (affirming district court’s denial of plaintiff’s motion to substitute new bellwether plaintiff; dismissal without prejudice “would set a precedent that other plaintiffs could use to manipulate the integrity of the court’s bellwether process”).

**b. The number and order in which the bellwether cases will be tried.**

As set forth above, Defendants propose that six bellwether Plaintiffs be selected from the existing bellwether candidate pool of 28 plaintiffs and worked up for individual trials. Defendants propose that, following the case workup and resolution of any Rule 702 and summary judgment motions, each side should select one case to be tried from the narrowed pool of six bellwether Plaintiffs and a random process applied to determine the order of the two trials.

Plaintiffs have indicated that they intend to propose a multi-plaintiff bellwether trial. Defendants are opposed to consolidation of multiple Plaintiffs’ cases for trial given the highly individualized nature of personal injury cases and the

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well-documented prejudice that multi-plaintiff trials cause defendants—unfairly skewing trials in plaintiffs’ favor and defeating the purpose of a bellwether trial.

At the bellwether stage, the goal should be to achieve valid tests, not to resolve large numbers of claims. Consolidation can tilt the playing field, undermining the goal of producing representative verdicts. As one transferee judge recognized in rejecting a proposal to hold a three-plaintiff bellwether trial, “[u]ntil enough trials have occurred so that the contours of various types of claims within the . . . litigation are known, courts should proceed with extreme caution in consolidating claims.” Consolidated bellwether trials may confuse juries, who are charged with wading through large quantities of complicated evidence to determine claims that may present different issues.

*See* Guidelines and Best Practices for Large and Mass-Tort MDLs 25 (2d ed. 2018); *see also Injectafer Prods. Liab. Litig.*, Nos. 19-276, 19-984, 2021 U.S. Dist. LEXIS 138685, at \*2 (E.D. Pa. July 26, 2021) (citation omitted) (denying consolidation because “modest gains in efficiency” did not justify “the spectre of prejudice should [the] actions be tried together”).<sup>2</sup>

While Defendants believe the Court should not permit multi-plaintiff bellwether trials, if the Court intends to consider it, Plaintiffs should be required to

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<sup>2</sup> *Accord* Chilton Davis Varner, *The Beginning of MDL Consolidation: Should Cases be Aggregated and Where?* 37 Rev. Litig. 227, 239 (2018) (noting the “breath-taking verdicts awarded thus far in multiple-plaintiff [MDL] ‘bundled’ trials”); Irwin A. Horowitz & Kenneth S. Bordens, *The Consolidation of Plaintiffs: The Effects of Number of Plaintiffs on Jurors’ Liability Decisions, Damage Awards, and Cognitive Processing of Evidence*, 85 J. Applied Psychol. 909 (2000) (study finding defendants more likely to be judged as liable, and that damages were more likely to be higher, when claims were consolidated for trial).

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move for consolidation after discovery is complete and the court can properly analyze whether the requirements of Rule 42 are satisfied. *See, e.g., In re Levaquin Prods. Liab. Litig.*, No. 08-1943 (JRT), 2009 U.S. Dist. LEXIS 116344, at \*10-11 (D. Minn. Dec. 14, 2009) (denying a motion for consolidation as “premature”; “if plaintiffs renew this motion at the close of discovery, the parties will be equipped to provide the Court with a clear synopsis – supported by the record – of the factual underpinnings of each case and a well-defined summary of the legal issues to be presented at trial”).

**c. The need for *Lexecon* waivers as to personal jurisdiction and venue, given the Court’s Case Management Order No. 3.**

Defendants agree that *Lexecon* waivers will be necessary for certain of the personal injury bellwether cases to the extent they are to be tried in the District of New Jersey. Defendants anticipate that certain individual Defendants may or may not waive *Lexecon* with respect to certain bellwether cases. Defendants are assessing and will continue to do so as the cases to be worked up for trial are identified from the bellwether pool. Defendants make clear, however that to the extent any Defendant executes a *Lexecon* waiver, that: (1) waiver would be limited to only the individual bellwether case proceeding to trial, and would not apply more broadly to other cases consolidated in the MDL; and (2) they will not waive *Lexecon* for multi-plaintiff trials.

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**d. The scope of any remaining fact (and expert) discovery for the bellwether cases selected for trial.**

One reason for narrowing the case pool is to make it feasible to complete fact discovery in each trial pool case in a timely manner. Defendants anticipate the need for the following fact discovery:

***Plaintiff-Specific Document Discovery.*** The parties will need to collect updated and complete medical, pharmacy, employment, disability, and workers' compensation records for each Plaintiff. In addition to the authorizations for releases of records, each PFS seeks the production of 23 categories of documents. Because most of the PFSs are dated in 2020 or 2021, the documents produced are similarly several years old. Thus, Defendants will require updated document productions. Depending on the facts of the selected bellwether cases at issue and information gleaned during the bellwether Plaintiffs' and their treaters' depositions, Defendants may also seek the production of additional materials specific to certain bellwether Plaintiffs.

***Depositions.*** Deposition discovery in these cases to date has been fairly limited. As noted above, the Plaintiff (or estate representative), a treating physician, and a prescribing physician have been deposed in each of the 28 cases. In order to prepare the cases for trial, Defendants will need to depose additional fact witnesses, including the Plaintiffs' family members and additional treating physicians or



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medical professionals. Some updates may also be required for prior depositions to the extent facts have changed, although Defendants hope to keep them to a minimum.

***Expert Discovery.*** Because the liability-expert-related discovery phase was largely focused on the TPP class Plaintiffs' economic loss claims against ZHP, Torrent and Teva, the parties will need to complete expert discovery, including both sides' expert reports and depositions, related to: (1) Plaintiffs' claims against the remaining Defendants; and (2) specific causation and damages related to Plaintiffs' personal injury claims.

**e. The designation of deposition testimony for bellwether trials, including the extent to which the deposition designations made in contemplation of the postponed TPP trial may be used in bellwether trials.**

Defendants believe that certain designations of ZHP, Torrent and Teva's witnesses made in contemplation of the postponed TPP trial may potentially be used in bellwether trials. However, Defendants note that only the TPP Trial Defendants participated in the deposition designation process, and after meeting and conferring it is apparent that both sides intend to revisit the current deposition designations dependent on the Court setting specific parameters for the bellwether trials and issues including, but not limited to, the nature of the evidence about general causation and/or cancer. Defendants do not intend to needlessly revisit Your Honor's rulings on deposition designations which are equally applicable but do not believe

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further hearings on specific designations are a productive use of the parties' or the Court's time at this juncture.

**f. The exchange of witness and exhibit lists for the bellwether trials.**

The parties met and conferred on October 16, 2024, and October 18, 2024, and appear to agree that the exchange of witness and exhibit lists for the bellwether trials can occur at a later date in connection with the pretrial order to be submitted for the bellwether trials once they are identified and set. Defendants propose that the parties include a deadline for the exchange of witness and exhibit lists in their proposed case management order discussed above.

**g. The submission of proposed jury instruction.**

Because the content of proposed jury instructions will depend on the specific claims at issue in each bellwether case and the state laws applicable to those claims, it would be premature for the Court to address jury instructions at this point. Defendants propose that, once the Plaintiffs whose claims will be at issue in the bellwether trials are selected, the parties be required to work together to develop proposed jury instructions. Defendants propose that the parties include a deadline for the submission of their proposed jury instructions with the case management order discussed above.

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**h. Whether defendants intend to call Maggie Kong and/or Jinsheng Lin as witnesses in the bellwether trials.**

The ZHP Defendants intend to call both Maggie Kong and Jinsheng Lin as fact witnesses in any bellwether trial involving claims against the ZHP Defendants.

**i. An identification of any outstanding disputes regarding the reports for, or discovery of, the causation expert witnesses.**

On March 18, 2022, Defendants filed a Joint Motion for Clarification Regarding *Daubert* Hearing Order 1 (“Motion for Clarification”). [ECF No. 1976](#). The Motion for Clarification relates solely to the NDEA impurity.<sup>3</sup> Therein, Defendants sought confirmation that Plaintiffs are permitted to pursue personal injury cases related only to pancreatic cancer<sup>4</sup> because the Court’s *Daubert* Hearing Order 1 expressly precluded three of Plaintiffs’ general causation experts from offering opinions regarding NDEA and any of the other twelve cancers at issue in

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<sup>3</sup> The at-issue valsartan manufactured by Defendants Mylan and Aurobindo did not contain NDMA above the allowable limits set by FDA. As a result, only NDEA is at issue with respect to those Defendants and their respective supply chains.

<sup>4</sup> It bears repeating that the opinions of these experts related to pancreatic cancer are premised on *a single dietary study* that identified a weak association between NDEA ingestion and pancreatic cancer. Accordingly, Plaintiffs’ overall case with respect to NDEA causation is tenuous, at best. *See In re Zolof (Sertraline Hydrochloride) Prods. Liab. Litig.*, No. 12-md-2342, 2015 WL 7776911, at \*3 (E.D. Pa. Dec. 2, 2015) (“Even where the confidence interval is narrow and the increased risk is statistically significant, scientists will not draw firm conclusions. from a single study, as apparent associations may reflect random error, bias, confounding, or some weakness in the study design, or they may be incongruous with existing scientific knowledge about biological mechanisms.”), *aff’d*, 858 F.3d 787 (3d Cir. 2017).

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the MDL proceeding, and Plaintiffs' remaining two general causation experts did not offer opinions about specific cancers. *See* [ECF No. 1958](#) at 2. Accordingly, Defendants understand *Daubert* Order 1 to preclude all causation evidence as to NDEA and any cancer type other than pancreatic cancer, and Defendants sought clarification on that basis.

Per agreement of the parties, and as instructed by the Court, adjudication of the Motion for Clarification was deferred while the focus of the MDL proceeding shifted to the class cases. Accordingly, Plaintiffs never filed a formal opposition, and the Motion for Clarification has been held in abeyance for the past two and a half years.

On a meet and confer last week, Plaintiffs indicated that they will ask the Court to decide the Motion for Clarification as soon as possible because it presents a "threshold issue" as to which bellwether cases, if any, can proceed against Defendants Mylan and Aurobindo, as well as their respective chains of distribution. Defendants agree that the Court should set a schedule for completion of the briefing and oral argument before Judge Bumb on this pending dispute.

In addition to filing an opposition to the Motion for Clarification, Plaintiffs have also indicated that at the outset of this process they intend to cross-move for reconsideration of the Court's general causation Rule 702 rulings that limited Plaintiffs' experts as to NDEA.

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**j. An identification of any Rule 702 issues that need to be resolved in advance of bellwether trials.**

Causation is the central issue in this MDL proceeding, and as outlined above and discussed previously with the Court, there are matters related to causation that will need to be resolved. Defendants have already expressed their concerns with the Court's Rule 702 rulings handed down in 2022, particularly given the recent amendments to Rule 702. *See* ECF No. 2770 at 46–51.

Particularly given Plaintiffs' intent to seek reconsideration of the Court's prior general causation rulings as to NDEA, Defendants believe that the Court's reevaluation should apply to all general causation issues. Specifically, the Court should employ the standards set forth in the recently-amended Rule 702 to determine whether Plaintiffs have satisfied their burden of proving through consistent, scientifically-reliable expert evidence that VCDs containing trace levels of NDMA and NDEA nitrosamines in VCDs can cause any of the cancers at issue.

As Defendants have previously indicated, *see* [ECF No. 2770](#) at 10–14, 46–51, Judge Bumb's reconsideration of the general causation *Daubert* rulings is warranted due to the recent amendments to Rule 702, as well as further evolution in the scientific literature. Defendants would invite the Court to direct the parties how best

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to proceed, whether through supplemental briefing, Rule 702 evidentiary hearings, or some other process.<sup>5</sup>

Additionally, Defendants anticipate the need for filing of Rule 702 motions and hearings as to specific causation and damages experts disclosed for individual personal injury bellwether cases selected for trial. Defendants propose that the parties include deadlines for the filing of Rule 702 motions as to case specific experts in their proposed Case Management Order discussed above.

**k. The need, if any, to supplement Plaintiff Fact Sheets.**

As noted above, plaintiffs should be required to update the individual PFSs for each Plaintiff in the bellwether candidate pool within one week of the October

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<sup>5</sup> To the extent the Court is inclined to reconsider the general causation *Daubert* rulings and preclude Plaintiffs' experts from testifying regarding cancer causation and NDMA/NDEA, that decision would be dispositive of the entire MDL proceeding, including the class cases. Indeed, this is precisely what occurred in the *Zantac* MDL. *See In re Zantac (Ranitidine) Prod. Liab. Litig.*, No. 20-MD-2924, 2023 WL 4765409, at \*1 (S.D. Fla. July 26, 2023) ("In light of its *Daubert* ruling, the Court undertook to determine whether the Plaintiffs still could move for certification of their medical monitoring and economic loss class action claims. In this Order, the Court sets forth why the Plaintiffs cannot do so."). This Court, too, has previously acknowledged that the causation issue controls the outcome of the class cases. *See, e.g.*, June 1, 2022 Hrg. Tr. at 19:22-20:14 (discussing issues of general causation and damages in the context of a TPP trial); Feb. 28, 2022 Hrg. Tr. at 41:8-12 (stating, "we'll pick a case if we have to, probably a third-party payor case . . . and just to get a jury to say yes or no on the question of general causation and get that done."); March 27, 2019 Hrg. Tr. at 4:12-16 (stating, "causation carries over" into all cases, including the economic loss class actions, because "if the contamination is not dangerous," then the consumer and TPP plaintiffs may not have suffered any economic injury).

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22, 2024 hearing. For the vast majority of these Plaintiffs, the PFSs have not been updated since 2021 at the latest. It is essential that the parties and the Court have up-to-date medical and other information relevant to each of these candidates prior to the selection of the bellwether Plaintiffs and the start of fact discovery so that those tasks can be completed in an effective and efficient manner. Current PFSs will allow the parties and the Court to more accurately determine the type and extent of injury alleged by each bellwether candidate and, once bellwether Plaintiffs are selected and determine whether additional medical or other witnesses should be deposed in connection with their cases. In short, the provision of updated PFSs is the first discovery step that should be taken in selecting and working bellwether cases up for trial.

**I. A schedule for the completion of punitive damages discovery.**

Defendants do not believe a schedule for the completion of punitive damages discovery is required at this time. In anticipation of the TPP Class Trial that was previously scheduled to begin in October 2024, the parties were in the process of negotiating stipulations regarding the TPP Trial Defendants' (ZHP, Torrent and Teva) financial condition and other punitive-damages-related information to be used at that trial. The TPP Trial Defendants anticipate that the parties will continue to negotiate such stipulations to the extent they are applicable in bellwether personal injury cases.

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**m. The submission of a Final Pretrial Order.**

The parties met and conferred on October 16, 2024 and October 18, 2024, and appear to agree that submission of a Final Pretrial Order is not needed until the first case to be tried is selected. The parties will meet and confer to utilize the draft already prepared and streamline the Final Pretrial Order to be submitted in connection with the next trial set by the Court to the extent practicable, and Defendants propose that a deadline for submission of a case-specific PTO can be included in the proposed case management order discussed above.

**n. Any other matter the parties would like to address at this time.**

While not necessarily something that must be resolved before a bellwether trial can proceed, the Court should require Plaintiffs to establish minimum thresholds of exposure in order to winnow the overall inventory of personal injury cases in the MDL, which currently account for around 98% of all consolidated cases. To effectuate this, other courts in alleged toxic exposure cases have applied the threshold dose approach. For example, in *Zantac*, which involved one of the same causation experts—Dr. Dipak Panigrahy—as well as one of the same impurities—NDMA—that are at issue here, the Court recognized the importance of threshold dose and required Plaintiffs’ experts to establish the same. *See In re Zantac (Ranitidine) Prod. Liab. Litig.*, 644 F. Supp. 3d 1075, 1109 (S.D. Fla. 2022) (“The Court concludes that the Plaintiffs must identify a threshold dose range at which



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ranitidine can cause cancer . . . . Courts universally reject general causation theories based upon the idea that any amount of a carcinogen, no matter how small, is actionable because an infinitesimal risk can neither be proven nor disproven.”). Ultimately, in *Zantac*, Dr. Panigrahy opined “that a person taking two tablets of ranitidine each day can reach a cumulative NDMA-exposure level of 5,990 micrograms and increase his risk of cancer significantly in 7.5 years for stomach, bladder, esophageal, and pancreatic cancers and in 14.3 years for liver cancer.” *Id.* at 1273. Notably, no plaintiff in this MDL proceeding could have ingested at-issue valsartan for more than six years.

Further, in the context of the certified medical monitoring classes here, Dr. Panigrahy calculated “lifetime cumulative thresholds” that would, in his view, justify lifetime monitoring for cancer. *See* Consolidated Third Amended Medical Monitoring Class Action Complaint, ¶ 541, [ECF No. 1709](#). Logically, if Plaintiffs believe these are the thresholds that put a plaintiff at risk to develop cancer, then the thresholds that would arguably support scientific causation of cancer must be the same *or higher*. Defendants would like an opportunity to discuss this proposal with Judge Bumb in connection with the general causation requests noted above.<sup>6</sup>

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<sup>6</sup> There are other types of motion practice and discovery that may help facilitate narrowing of the litigation and legal issues involving the personal injury cases. Defendants expressly reserve all rights to address cases other than the identified bellwethers through other types of motion practice and discovery. Consistent with

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Defendants look forward to discussing these issues and any others the Court wishes to address at the upcoming Case Management Conference.

Sincerely,

/s/ Victoria Davis Lockard  
Victoria Davis Lockard, Esq.

cc: All counsel of record (via ECf)

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the Court's directive, however, this letter is primarily focused on bellwether selection and workup.